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10/596,158

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Hans Jorg Meisel

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SUTHERLAND ASBILL & BRENNAN LLP
999 PEACHTREE STREET, N.E.
ATLANTA, GA 30309

EXAMINER

SCHNEIDER, LYNN SY M

ART UNIT

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3733

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,158	Applicant(s) MEISEL, HANS JORG	
	Examiner LYNNSY SCHNEIDER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8, 9, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 8, 9, 18, and 19 recite the broad recitation of the base parts or the coupling parts being coated, and the claim also recites both the base parts and the coupling parts being coated which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-7, 9-16, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Istephanous et al. (Pub. No. US 2004/0243241 A1).

6. Regarding claims 1 and 11, Istephanous et al. disclose a prosthesis comprising two base parts 102 and 104 (figure 8) which are coupled to one another in an articulated manner by means of coupling parts 70 and 74 formed on the base parts, as labeled in figure 6. Although figures 5 and 6 represent a different embodiment than figure 8, paragraphs 0073 and 0074 disclose that base parts 102 and 104 can be provided substantially as has been described for base parts 52 and 54 from implant 50, which is represented in figure 6. Figure 8 shows that the base parts 102 and 104 are in each case formed in one piece with an associated coupling part 70 and 74, wherein the base parts 102 and 104 and the coupling parts 70 and 74 are made of a material selected from the following group of materials; polyetherketone (PEK), polyetheretherketone (PEEK), polyetherketoneketone (PEKK) (paragraph 0083).

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7. Regarding claims 2 and 12, Istephanous et al. disclose that an anatomically adapted contact surface is formed on a respective outer side of the two base parts (figure 7). As stated for claims 1 and 11, although figure 7 is a different embodiment from the implant of figure 8, Istephanous et al. disclose, in paragraphs 0073 and 0074, that base parts 102 and 104 can be provided substantially as has been described for base parts 52 and 54 from implant 50, which is represented in figure 7. Therefore, since figure 7 shows the outer side of base parts 52 and 54 contacting the vertebrae, it can be concluded that base parts 102 and 104 also include anatomically adapted contact surfaces on the outer side.

8. Regarding claims 3 and 13, Istephanous et al. disclose that an anti-rotation means 112 and 114 (figure 8) is formed on the outer side of each of the two base parts 102 and 104 (paragraph 0074).

9. Regarding claims 4 and 14, Istephanous et al. disclose that the anti-rotation means comprises a web 112 and 114 arranged on the respective outer side (figure 8 and paragraph 0074).

10. Regarding claim 5, Istephanous et al. disclose that the two base parts 102 and 104 are coupled to one another in an articulated manner by means of a sliding connection (paragraph 0066).

11. Regarding claim 6, Istephanous et al. disclose that the sliding connection is embodied by means of a sliding surface formed on one of the coupling parts 70 (figure 6) and a countersliding surface, which is adapted to the sliding surface and is formed on another of the coupling parts 74 (figure 6), wherein the sliding surface is slidably

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supported on the countersliding surface in the coupled state of the two base parts 102 and 104 (figure 8 and paragraph 0066).

12. Regarding claim 7, Istephanous et al. disclose that the sliding surface is formed on a hemispherical protrusion on the coupling part 70 (figures 6 and 8).

15. Regarding claim 9, Istephanous et al. disclose that the two base parts 102 and 104 and/or the coupling parts 70 and 74 are at least partially coated (paragraphs 0037 and 0041).

13. Regarding claims 10 and 19, Istephanous et al. disclose that the anatomically adapted contact surfaces 115 and/or the webs 112, 114 have a material coating (paragraphs 0037 and 0041).

14. Regarding claim 15, Istephanous et al. disclose that a sliding surface is formed on the coupling part 70 (figure 6 and paragraph 0066).

15. Regarding claim 16, Istephanous et al. disclose that the sliding surface on coupling part 70 is curved (figures 6 and 8).

16. Regarding claim 18, Istephanous et al. disclose that an at least partial material coating of the base parts 102/104 and/or of the coupling part 70/74 is provided (paragraphs 0037 and 0041).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Istephanous et al. in view of Ogle et al. (Pat. No. US 6,322,588 B1).

19. Regarding claims 8 and 17, Istephanous et al. disclose all of the claimed elements, except for the sliding surface and the countersliding surface being coated with a coating material based on a chromium-nickel alloy. However, Ogle et al. teaches coating medical implants, and particularly spinal implants (col. 3, lines 44-45) with a cobalt-nickel-chromium alloy (col. 4, lines 13-23) for the purpose of improving the mechanical properties of the implants (col. 2, lines 25-34). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to coat the spinal implant of the Istephanous et al. reference with a cobalt-nickel-chromium alloy as taught by Ogle et al. for the purpose of improving the mechanical properties of the spinal implant.

Response to Arguments

20. Applicant's arguments filed 6/17/2009 have been fully considered but they are not persuasive.

21. Applicant argues that the Istephanous reference does not disclose a base part and a coupling part formed in one piece and made from a material selected from polyetherketone (PEK), polyetheretherketone (PEEK), polyacryletherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneetherketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK). Applicant argues that since the reference teaches that, in one embodiment, the projection is formed of a metal matrix composite

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and the trough is formed of a metal matrix composite, and the upper portion, lower portion, projection, and trough are formed of the same material, the material is a metal matrix composite.

22. This argument is not persuasive. Applicant is drawing conclusions based on the teachings for one embodiment of the invention in which the protrusion is disclosed as being made of a metal matrix material. However, alternative embodiments and modifications are disclosed by Istephanous. Figure 6 clearly shows that the device consists of two discrete pieces, an upper piece 52, and a lower piece 54. Projection 70 is part of the discrete upper piece, as shown in figure 6. Figure 6 is an exploded view of the implant (paragraph 0013). Thus, if projection 70 were a separate piece, it would be shown as such in figure 6. Paragraphs 0067 and 0068 disclose that both upper and lower portions 52 and 54 (which include projection 70 and trough 74, respectively) can be formed of a biocompatible material that is not a metal matrix composite (paragraph 0067), the non metal matrix composite material comprising a polymeric material (paragraph 0068). Paragraph 0083 lists suitable polymers for use with the invention, the list including PEK, PEEK, PEKK, etc. Therefore, Istephanous discloses the claimed invention, including two base parts with associated coupling parts formed thereon, the base parts and the coupling parts being made of a material selected from PEK, PEEK, PAEK, PEKK, PEKEKK, and PEKEK.

23. Applicant argues that since Istephanous et al. teaches an implant formed of a metal matrix composite, it teaches away from modification of the implant to include a metallic coating. However, as stated above, Istephanous et al. discloses a polymeric

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implant. Therefore, for the reasons stated above, Istephanous et al. does not teach away from modification of the implant to include a metallic coating.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733